UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

IN RE: ZETIA (EZETIMIBE) ANTITRUST LITIGATION	:	
	:	**MDL No. 2:18-md-2836**
THIS DOCUMENT RELATES TO: All Actions	:	

REPORT AND RECOMMENDATION

In this multidistrict litigation, Plaintiffs allege that Defendants Merck[1] and Glenmark[2] (collectively "Defendants") conspired to delay generic competition for the branded cholesterol medication Zetia by artificially prolonging its patent protection. Using the framework established in Federal Trade Commission v. Actavis, 570 U.S. 136 (2013), Plaintiffs allege that a settlement Defendants reached in their underlying patent litigation contained a large and unjustified reverse payment. They assert that Merck promised not to launch its own generic to compete with Glenmark in exchange for Glenmark's agreement to delay generic entry. Defendants claim no reasonable juror could find that Merck's deal with Glenmark had the anticompetitive affects alleged and seek summary judgment on all claims.

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[1] "Merck" consists of Merck & Co., Inc.; Merck Sharp & Dohme Corp.; Schering-Plough Corp.; Schering Corp.; and MSP Singapore Co. LLC.

[2] "Glenmark" consists of Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA, the latter incorrectly identified as Glenmark Generics Inc., USA.

Both motions were referred to me to prepare a recommended disposition. My review of the record produced on summary judgment establishes triable issues on several elements of the claims Plaintiffs allege. These disputes of material fact preclude entry of judgment in favor of Defendants' as a matter of law. Accordingly, as set out in detail below, this report RECOMMENDS the court DENY Defendants' motions for summary judgment (ECF Nos. 1037, 1067).

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I. BACKGROUND

The allegations underlying this multidistrict litigation have been set forth in previous opinions.[3] A summary of the facts relevant to this motion is set forth below.

A. Background on Regulatory Approval to Sell Generics

A company must request approval from the Food and Drug Administration ("FDA") before it can market a pharmaceutical product. Jon Clark Expert Report ("J. Clark Rpt.") ¶ 14 (ECF No. 1148-2, at 7). The applicable regulatory framework is the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), which allows the original manufacturer to request approval by filing a New Drug Application ("NDA").

If a drug was previously approved under an NDA, subsequent generic manufacturers can obtain approval with a smaller expenditure of resources under the FDA's Abbreviated New Drug Application ("ANDA") process, which relies on the original NDA. Id. ¶¶ 14, 22-26 (ECF No. 1148-2, at 7, 9-10). ANDA filers must make certain representations about the brand manufacturer's patent, including whether applicable patents will, or have expired. 21 U.S.C. § 355(j)(2)(A)(vii), (I-IV). A Paragraph IV

[3] In re Zetia (Ezetimibe) Antitrust Litig., No. 2:18-md-2836, 2019 WL 6122017, at *1-3 (E.D. Va. Oct. 15, 2019), R. & R. adopted as modified, 2019 WL 6977405 (E.D. Va. Dec. 20, 2019); In re Zetia (Ezetimibe) Antitrust Litig., No. 2:18-md-2836, 2019 WL 1397228, at *1-10 (E.D. Va. Feb. 6, 2019), R. & R. adopted as modified, 400 F. Supp. 3d 418 (E.D. Va. 2019).

filing, as relevant here, requires certification that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]" § 355(j)(2)(A)(vii)(IV).

To provide incentives for generics to enter the market, an ANDA first filer enjoys a statutory 180-day exclusivity period, which generally begins upon marketing the generic. § 355(j)(5)(B)(iv). The exclusivity period does not apply to the original manufacturer, which can choose to market an authorized generic ("AG") under the original NDA. § 355(t)(3)(B). An AG is defined in the Hatch-Waxman Act as one approved under an NDA and "marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging . . . . , product code, labeler code, trade name, or trade mark than the listed drug." Id.

B. Merck-Glenmark Litigation

In the 1990s, Merck prosecuted a series of patents for azetidinone compounds. DPPs' Am. Compl. ¶ 102 (ECF No. 128, at 37); EPPs' Am. Compl. ¶ 107 (ECF No. 130, at 40). One of the patents Merck obtained was U.S. Patent No. 5,767,115 (the "RE'115 Patent"), which the United States Patent and Trademark Office eventually reissued as U.S. Patent No. RE37,721 (the "RE'721 Patent"). Robert Hrubiec Expert Report ("Hrubiec Rpt.") ¶¶ 28-29, 33 (ECF No. 1083-18, at 18, 19-20). These patents covered

ezetimibe, the active pharmaceutical ingredient in Zetia. See Merck Mem. Statement Facts[4] ("Merck SOF") ¶ 2 (ECF No. 1085, at 11-12); Pls.' Opp'n (ECF No. 1156, at 14). Merck also obtained approval from the Food and Drug Administration ("FDA") to market Zetia (branded ezetimibe) on October 25, 2002. Merck SOF ¶ 5 (ECF No. 1085, at 12).

In October 2006, Glenmark became the first to file an ANDA for Zetia, which Glenmark submitted under Paragraph IV. Merck SOF ¶ 9 (ECF No. 1085, at 12); Glenmark Mem. Statement Facts ("Glenmark SOF") ¶ 5 (ECF No. 1050, at 11-12). After receiving notice of Glenmark's ANDA filing, Merck sued in the United States District Court for the District of New Jersey alleging that Glenmark's generic would infringe the RE'721 Patent. Merck SOF ¶ 10-11 (ECF No. 1085, at 13). Glenmark stipulated to infringement but counterclaimed that the RE'721 Patent was either invalid or unenforceable on several bases. Id. ¶ 12. Glenmark's claims were based on improper reissue, obviousness-type double patenting ("ODP"), failure to name an inventor (the "Inventorship Defense"),

[4] Facts that Plaintiffs do not dispute are taken as true for the purposes of these motions. Undisputed facts appear in both Merck's and Glenmark's memoranda supporting their respective motions for summary judgment. In the interest of space, parallel citations to both statements of facts are not always provided. For disputed facts, citations also include "the parts of the record relied on to support the facts alleged to be in dispute." Local Civil Rule 56(B).

and inequitable conduct committed during the patent-term extension period. Hrubiec Rpt. ¶ 52 (ECF No. 1083-18, at 29-30).

In its Inventorship Defense Glenmark claimed invalidity or unenforceability based on Merck's failure to name Dr. Adriano Afonso ("Afonso") as an inventor of Compounds 4E/F, which were claimed in the RE'115 Patent and the later reissued RE'721 Patent. Hrubiec Rpt. ¶¶ 193-99 (ECF No. 1083-18, at 87-89); see also DPPs' Am. Compl. ¶ 163 (ECF No. 128, at 54). The RE'721 Patent named Dr. Stuart Rosenblum ("Roseblum") as an inventor. Hrubiec Rpt. ¶ 30 (ECF No. 1083-18, at 19). Glenmark argued that Afonso, not Rosenblum, invented Compounds 4E/F because Afonso discovered the operative method of synthesizing them. Id. ¶¶ 193-99 (ECF No. 1083-18, at 87-89). Glenmark's Inventorship Defense thus hinged on whether Afonso was a co-inventor of Compounds 4E/F and should have been disclosed as an inventor of the RE'721 Patent to the PTO. Id. ¶¶ 208-09 (ECF No. 1083-18, at 93). After extensive motions practice and discovery, the case was set for trial on May 12, 2010. Id. ¶ 14 (ECF No. 1085, at 14). On May 10, 2010, two days before trial, the parties settled. Settlement Agreement ("Sett. Agr.") (ECF No. 398-21).

C. Merck-Glenmark Settlement

Settlement negotiations between Merck and Glenmark began in mid-2009. Glenmark SOF ¶ 10 (ECF No. 1050, at 13). Dr. Vijay Soni ("Soni") was Glenmark's chief negotiator. Id. ¶ 9. Henry

Hadad ("Hadad") originally negotiated on behalf of Schering, but after Schering merged with Merck, Paul Matukaitis ("Matukaitis") acted as Merck's chief negotiator. Id.

1. Settlement Negotiations

Among the terms the parties discussed were provisions allowing Glenmark to enter the market before the RE'721 patent expired, and limiting Merck's ability to launch its own generic version of ezetimibe. In June 2009, Terrance Coughlin, Glenmark's U.S. CEO, emailed Soni that Par Pharmaceuticals[5] thought it could "get 12-18 months prior to patent expiry," to which Soni responded that "[g]etting 12 (maybe 18 also) months prior to patent expiry is something we can also try (+ we can try [to] ask for our legal cost)." Pls.' Ex. 79 (ECF No. 1131-11) (cleaned up). In August 2009, after communicating with Hadad, Soni reported to Glenmark executives that he thought Merck might "be open" to about six months early entry for ezetimibe, but he expected early entry would "be negotiated down to 3-4 months." Merck Ex. 33 (ECF No. 1082-8, at 2, 3); see Merck SOF ¶ 19 (ECF No. 1085, at 15).

Soni's negotiation notes record that, in November 2009, Glenmark made a demand for six months early entry and "NO AG for

[5] Par Pharmaceuticals was expected to, and eventually did, partner with Glenmark to sell its generic ezetimibe. Par was involved, through Glenmark, in the settlement negotiations with Merck. Par settled with Plaintiffs early in this litigation. Order Approving Settlement (ECF No. 898).

Zetia." Merck Ex. 36 (ECF No. 1082-11, at 2). On February 25, the same notes reflect Merck countered with one month early entry but was silent on a Zetia AG. Id. The following day, Glenmark countered for five months early entry and "No AG Zetia/AG for Vytorin," which term Soni circled in his notes. Id. Soni also emailed Matukaitis stating that he "realized that [he] missed one point from [his] end . . . No AG for Zetia for 6 Month period (during our exclusivity)." Glenmark Ex. 19 (ECF No. 1039-19, at 2). Soni's notes show that Merck responded on March 1 with two months early entry and "No AG for Zetia : NO," and Soni circled both terms and drew a line between them. Merck Ex. 36 (ECF No. 1082-11, at 2). Plaintiffs assert that the NO after the colon "corresponds to Glenmark's additional request for the Vytorin AG, not the Zetia no-AG." Pls.' Opp'n (ECF No. 1156, at 16). Defendants contend that the NO refers to Zetia. Merck Reply (ECF No. 1213, at 12).

Defendants also rely on deposition testimony, the accuracy of which Plaintiffs vigorously dispute. See Pls.' Opp'n (ECF No. 1156, at 15) (asserting that their evidence "describes various payments to Glenmark bundled with and affecting Glenmark's entry date, contradicting the defendants' testimony"). Soni testified that he believed Merck would only agree to a "maximum three to four months" of early entry. Soni Dep. 228:21-229:10 (ECF No. 1079-15, at 15-16). He also testified that Merck said "no" to a

no-AG provision for Zetia. Id. 112:3-15 (ECF No. 1079-15, at 10). Matukaitis testified that that Merck was "not going to give a no-AG clause . . . [but could] give a limited exclusive license in a field." Matukaitis Dep. 206:8-14 (ECF No. 1082-9, at 26). Both negotiators testified that there was no link between the request for a no-AG provision and the early entry date. See, e.g., Soni Dep. 228:3-20 (ECF No. 1079-15, at 15) (testifying that a no-AG term "did not have any" effect on the entry date); Matukaitis Dep. 229:6-23 (ECF No. 1082-9, at 33) ("It was not linked. There was never a link.").

On March 29, 2010, Merck sent Matukaitis the first draft of the settlement agreement, which provided for two months of early entry on February 25, 2017. Merck Ex. 38 (ECF No. 1082-13, at 11). It also contained two definitions, one for "Authorized Generic," and one for "Generic Ezetimibe." Id. at 5-6. The term Authorized Generic was defined in the draft as "a pharmaceutical product containing ezetimibe as its sole active ingredient that is manufactured, sold, offered for sale, or distributed pursuant to NDA No. 21-445 but is not sold under the trade name Zetia or another trademark or tradename of Schering or its affiliates." Id. at 5. By May 2010, settlement drafts contained an entry date of December 12, 2016. Merck Ex. 40 (ECF No. 1082-15, at 12); Merck Ex. 41 (ECF No. 1082-16, at 13); Merck Ex. 42 (ECF No. 1082-17, at 13). The drafts also removed the definition of "Authorized

Generic" and included a revised definition of "Generic Ezetimibe," which incorporated most of the language previously used to define the term "Authorized Generic." See Merck Ex. 42 (ECF No. 1082-17, at 5-6).

2. Terms of the Final Merck-Glenmark Settlement Agreement

On May 10, 2010, Merck and Glenmark signed the Settlement Agreement. Sett. Agr. (ECF No. 398-21). Under its terms, Glenmark could launch its generic ezetimibe product on December 12, 2016. Id. § 5.4 (ECF No. 398-21, at 13). Merck also agreed to reimburse Glenmark for up to $9 million in attorneys fees. Merck SOF ¶ 35 (ECF No. 1085, at 18-19). Merck had incurred $21 million in legal fees up to that point. Id.

The Settlement Agreement granted Glenmark an exclusive right to market "Generic Ezetimibe," during its period of exclusivity as the first filer under 21 U.S.C. § 355(j)(5)(B)(iv). Sett. Agr. § 5.3 (ECF No. 398-21, at 12-13). And, "Generic Ezetimibe" is defined in the Settlement Agreement as

> a drug product containing ezetimibe as its sole active ingredient (a) that refers to the Approved Zetia Product as the reference-listed drug in an ANDA . . . or (b) that is sold pursuant to NDA No. 21-445 but is not sold under the trademark Zetia® or another trademark or trade name of Schering, MSP or their Affiliates.

Id. § 1.14 (ECF No. 398-21, at 6) (emphasis added). In other words, the final draft of the Settlement Agreement defined "Generic Ezetimibe" to include versions of ezetimibe approved under an ANDA

filing, and the description formerly used in the draft to define Authorized Generic. Plaintiffs thus contend that this definition is a no-AG Agreement granting Glenmark an exclusive license to market all generic ezetimibe during its period of exclusivity. Pls.' Statement Facts ("Pls.' SOF") ¶¶ 7-8 (ECF No. 1156, at 25-26) (disputed). Defendants contend that this definition provides only a "limited exclusive license." Merck Mem. (ECF No. 1085, at 29). Interpreting the language of the Settlement Agreement, Matukaitis testified that Merck "could launch an authorized generic . . . if it had a trade name or trademark of Merck used in connection with that product." Matukaitis Dep. 211:22-212:7 (ECF No. 1082-9, at 27-28).

Others involved in the negotiation testified that Merck would not agree to a no-AG provision. Soni testified that Merck's negotiators made it "very clear" to him that they would not agree to a no-AG provision. Soni Dep. 112:3-116:22 (ECF No. 1079-15 at 10-14). Lawrence Brown, general counsel for Par likewise stated that the company "did not intend to include a no-authorize[d] generic clause in the agreement. Ex. 43, Brown Dep. 258:9-14 (ECF No. 1082-18, at 3).

A copy of the settlement was provided to the Department of Justice and the Federal Trade Commission ("FTC"). Merck SOF ¶ 36 (ECF No. 1085, at 19).

3. Post-Settlement Interpretations of the Asserted no-AG Provision

On May 11, 2010, Glenmark's U.S. CEO Coughlin emailed his boss that the "[f]acts of the deal" included "[n]o AG during" a list of possible scenarios for Glenmark's exclusivity period. Pls.' Ex. 160 (ECF No. 1159-11, at 2). Glenmark also sought investments and made revenue modeling decisions based on launching the generic without generic competition from Merck. Pls.' SOF ¶¶ 14-17 (ECF No. 1156, at 27-28).[6] In March 2015, at Glenmark's request, an attorney at Greenberg-Traurig opined that the Settlement Agreement "squarely addresses and precludes the launch of an AG (third party or not) during Glenmark's period(s) of exclusivity for 'distribution and sale of Generic Ezetimibe,' and that the parties specifically intended for it to do so." Pls.' Ex. 184 (ECF No. 1157-23, at 4). A 2016 Merck slide deck records that Merck could not "launch AGx" for Zetia because of the Settlement Agreement. Pls.' Ex. 111 (ECF No. 1152-14, at 15).

In 2016, Merck notified Glenmark of its view that the Settlement Agreement permitted the company to launch a Zetia AG 45 days before Glenmark's 180-day exclusivity period ended, or after April 25, 2017, when Merck's patent rights under the RE '721 patent

[6] Defendants do not dispute these records, only that "various post-settlement interpretations of the settlement agreement as well as actions by Merck with products other than ezetimibe" do not "refer to or discuss whether there was any sort of exchange during the settlement negotiations." Glenmark Reply (ECF No. 1195, at 13).

expired. Merck Ex. 47 (ECF No. 1082-22). Glenmark disagreed, noting its exclusive rights extended for the full 180-day period provided by its first filer status. Pls.' Ex. 97 (ECF No. 1151-12, at 3) (finding "no support" for Merck's argument). Merck signed a distribution and supply agreement with a distribution company, Pls.' Ex. 120 (ECF No. 1139-12), and began working toward an AG launch on May 22, 2017, Pls.' Ex. 122 (ECF No. 1153-6, at 5). In May 2017, Glenmark notified Merck that it was aware of the proposed AG launch and threatened suit. Pls.' Ex. 99 (ECF No. 1152-3). Merck canceled the AG launch. Pls.' Ex. 123 (ECF No. 1153-7, at 4); Pls.' Ex. 118 (ECF No. 1139-11, at 4).

D. Glenmark's Manufacturing Concerns

In addition to regulatory approval to sell a pharmaceutical product, generic manufacturers must be able produce enough product to supply anticipated demand. Marchetti Dep. 9:14-10:8 (ECF No. 1039-27, at 3-4). Every drug contains at least one active pharmaceutical ingredient ("API") that causes the pharmacological effect. J. Clark Rpt. ¶ 27 (ECF No. 1148-2, at 10). A drug manufacturer may produce its own API or source the API from a third party. See id. ¶¶ 43-45 (ECF No. 1148-2, at 15-16).

Early in its preparations, Glenmark experienced difficulties producing its own ezetimibe API. See Dutra Dep. 182:12-21, 187:23-188:15 (ECF No. 1039-21, at 4, 5). Before its launch in December 2016, Glenmark needed to acquire additional API from a third-party

source, MSN Laboratories ("MSN Labs"). Glenmark SOF ¶ 42 (ECF No. 1050, at 20); see also Pls.' Opp'n (ECF No. 1156, at 23). Glenmark had received pricing from MSN Labs for ezetimibe API beginning in 2008. Pls.' SOF ¶ 65 (ECF No. 1156, at 41). By November 2013, MSN Labs could produce more than 250 kg per month of the ezetimibe API. Id. ¶ 66 (ECF No. 1156, at 42).[7]

E. Mylan Litigation

At the time of its settlement with Glenmark, Merck was also suing Mylan, the first ANDA filer for generic Vytorin.[8] Merck Mem. ¶¶ 38-47 (ECF No. 1085, at 19-22). Mylan similarly claimed that the RE'721 Patent was invalid or unenforceable. Id. ¶ 38 (ECF No. 1085, at 19-20). In June 2010, after the Merck/Glenmark settlement, the RE'721 Patent was reissued as U.S. Patent No. RE42,461 (the "RE'461 Patent"), which Merck then asserted against Mylan. Id. ¶ 43 (ECF No. 1085, at 21). In its reissue application Merck cancelled all claims related to compounds 4E and 4F. Id.

[7] At oral argument on summary judgment, Glenmark vigorously contested the sufficiency of Marchetti's testimony on MSN's manufacturing capacity, complaining that it was speculative in light of her limited awareness of MSN's operations. Summ. J. Hearing Tr. (Hearing Tr.) at 53-57 (ECF No. 1693). Neither Defendant moved to exclude her opinion on this (or any other) basis, and I find the evidence she relied on, which included written evidence of MSN's capacity to produce 50 kg batches of ezetimibe in November 2013 and email correspondence regarding the company's ability to meet the demand adequate factual support for her testimony. This is particularly true in light of the absence of any testimony or evidence contradicting it. Hearing Tr. at 58 (ECF No. 1693).

[8] Vytorin is a combination drug comprised of ezetimibe (branded Zetia) and a statin, namely simvastatin. Merck Mem. ¶ 8 (ECF No. 1085, at 12).

¶ 52. Merck also changed its expert disclosures in the Mylan case, identifying Dr. Roush as an expert on inventorship. Id. ¶ 55. In December 2011, Mylan and Merck went to trial. Id. ¶ 45. U.S. District Judge Jose L. Linares found that the RE'461 Patent was valid and enforceable. Merck Ex. 71 (ECF No. 1083-21).

F. Relevant Plaintiffs' Expert Testimony

Defendants moved to exclude several experts whose testimony is relevant to this motion. This Report assumes that the experts would be permitted to testify as I have ruled in other decisions.[9] Their relevant opinions are described briefly below.

1. Robert Hrubiec

Robert Hrubiec ("Hrubiec") is Plaintiffs' patent merits expert. He intends to testify about how Merck and Glenmark would have evaluated their chances of litigation success when they settled in May 2010. Hrubiec opines that reasonable and competent patent counsel would have advised Merck and Glenmark that (1) Glenmark had a 65-75% chance of success against Merck, Hrubiec Rpt. ¶ 303 (ECF No. 1083-18, at 135-36); (2) litigation could have resolved in January 2014 after an appeal to the Federal Circuit, a remand, and a second appeal, id. ¶ 52.2 (ECF No. 1083-18, at

[9] Defendants may object to my opinions and seek review by the District Judge. Fed. R. Civ. P. 72. The U.S. District Judge will then review those portions objected to for clear error. Id. To the extent the District Judge rejects or modifies my rulings on the admissibility of these expert opinions, the underpinnings of this recommendation on summary judgment may be impacted.

30); see also Hrubiec Reb. Rpt. ¶ 84 (ECF No. 1084-17, at 70) (correcting to 2014); and (3) Merck and Glenmark saved $5 million each in litigation expenses by settling, Hrubiec Rpt. ¶ 52.3 (ECF No. 1083-18, at 31).

Hrubiec also explains why he believed Glenmark was likely to prevail, even though Merck successfully defended the ezetimibe patent in the Mylan litigation. In his rebuttal report, he expounds on several material differences in how Glenmark would have prosecuted its case differently in May 2010, than Mylan did the following year. See Hrubiec Reb. Rpt. ¶ 3 (ECF No. 1084-17, at 4-5).

First, Hrubiec notes that the Glenmark litigation involved the RE'721 Patent, while the Mylan litigation involved a reissued patent, the RE'461 Patent, which did not include key Compounds 4E and 4F. Id. ¶¶ 10-12 (ECF No. 1084-17, at 12-13). Hrubiec opines that this caused Mylan to take a different strategy than Glenmark, attempting to prove that Afonso was a co-inventor of ezetimibe as well as Compounds 4E/F. Id. ¶ 14 (ECF No. 1084-17, at 13-14). Pls.' SOF, ¶ 54 (ECF No. 1056, at 38).

Second, Hrubiec explains that Judge Linares rested his holding in Merck's favor on testimony from Merck's new expert on inventorship, Dr. Roush, that another chemist could have made Compounds 4E/F "after routine experimentation" based on his ability to synthesize another compound. Hrubiec Reb. Rpt. ¶ 16

(ECF No. 1084-17, at 15-17) (quoting Schering Corp., 2012 WL 1473329, at *15); Pls.' SOF, ¶ 55 (ECF No. 1156, at 38-39). Roush was not identified on this subject in the Glenmark case and Hrubiec opines that the absence of Roush's opinion in the Glenmark litigation "would be enough of a difference to render the Mylan litigation outcome completely irrelevant to assessing the likelihood of success in the Glenmark litigation." Hrubiec Reb. Rpt. ¶ 16. He considers this piece of evidence a linchpin in Judge Linares's holding. Id. Hrubiec also explains the impact of different counsel, as well as the opportunity afforded Mylan's counsel to learn from Glenmark's prior experience. Id. ¶ 18 (ECF No. 1084-17, at 18-19). Pls.' SOF, ¶ 56 (ECF No. 1156, at 39).

Lastly, Hrubiec explains how the Federal Circuit's holding in Therasense II constitutes a material difference between the Mylan and Glenmark litigations. Id. ¶ 19 (ECF No. 1084-17, at 19-20). He opines that Judge Linares "clearly, expressly and specifically" relied on Therasense II in deciding intent to deceive in the Mylan litigation. Hrubiec Reb. Rpt. ¶ 21 (ECF No. 1084-17, at 20). Pls.' SOF, ¶ 57 (ECF No. 1156, at 37).

2. Thomas McGuire and Keith Leffler

Thomas McGuire ("McGuire") and Keith Leffler ("Leffler") are Plaintiffs' expert economists. They intend to testify that, without the no-AG provision, Merck and Glenmark would have been economically incentivized to settle the underlying patent claims

with an earlier generic entry date than December 2016. Both McGuire and Leffler use models to predict alternative settlement conditions with data inputs representing the parties' expectations regarding the strength of their litigation positions at the time of settlement in May 2010, and the expected value of Merck's agreement not to launch an AG. McGuire estimates the no-AG promise was worth $62.3 million to Glenmark (McGuire Rpt. ¶ 112) (ECF No. 1130-8) while Leffler valued the benefit at $125 million. Leffler Rpt. ¶ 70 (ECF No. 1130-4, at 45). McGuire predicts that an economically rational settlement without this reverse payment would have allowed generic entry "between January 2015 and May 2015," McGuire Reb. Rpt. T2 (ECF No. 1130-9, at 26), while Leffler identifies April 1, 2015, Leffler Rpt. ¶ 85 (ECF No. 1130-4, at 54-55); Pls.' SOF ¶ II(e) (ECF No. 1156, at 15).

3. Generic Readiness Experts

Plaintiffs offer several experts on whether Glenmark or other generic manufacturers could have launched generic ezetimibe earlier than December 2016.

a. Susan Marchetti

Susan Marchetti ("Marchetti")[10] opines that Glenmark could have launched on November 15, 2014, or later with "quantities

[10] Defendants have not sought to exclude Marchetti in a dedicated motion in limine, but Glenmark argues in this motion that Marchetti's opinion is unfounded. Glenmark Mem. (ECF No. 1050, at 47-49). I thus address the reliability of Marchetti's opinion in the Analysis below.

sufficient to meet day-1 demand . . . and to meet continuing demand thereafter through December 12, 2016." Susan Marchetti Rpt. ¶ 28 (ECF No. 1148-13, at 13), Pls.' SOF ¶ 32 (ECF No. 1156, at 42). Marchetti relies on a set of Certificates of Analysis ("COA") from MSN Labs showing that it manufactured three batches of ezetimibe weighing approximately 50 kgs each within a two-week period in November and December 2013. Marchetti Rpt. ¶ 90 (ECF No. 1148-13, at 37). Marchetti then opines that MSN Labs' could have produced at least 250 kgs of the ezetimibe API per month in 2014. Id. ¶ 91 (ECF No. 1148-13, at 38); see also Marchetti Dep. 284:15-21 (ECF No. 1039-27, at 14) ("[M]y calculation in the production plan that [MSN Labs] could make 250 kilos a month was based on the demonstrated capacity that I saw that they had in November and December 2013."). Using that production rate, as well as Glenmark's production rates, Marchetti opines that Glenmark could have met market demand. Marchetti Rpt. ¶ 97 (ECF No. 1148-13, at 40).

In her deposition, Marchetti testified that she did not "know how [MSN Labs] structure[d]" its COAs, but that in her experience, the API "would have been manufactured to completion" within the timeframes she interpreted from the COAs. Marchetti Dep. 261:7-14 (ECF No. 1039-17, at 10). Marchetti also did not know the number of steps involved in MSN Labs' production process. Id. 127:21-128:5 (ECF No. 1039-27, at 6). But she testified that she

did not necessarily need to have information about MSN Labs' "facilities, equipment, and workforce" because a supplier's offer was evidence of capacity. Id. 124:20-125:9 (ECF No. 1037-27, at 5).

b. Jon Clark

Jon Clark evaluated different filing scenarios through which Glenmark could have obtained final approval depending on the Drug Master File ("DMF")[11] referenced in its ANDA. J. Clark Rpt. ¶¶ 104-09 (ECF No. 1148-2, at 39-40); Pls.' SOF ¶¶ 62-64 (ECF No. 1156, at 40-41). He identified two filing methods that could have produced approval by either January 2011 or June 2014. Jon Clark Rebuttal Report ("J. Clark Rbt. Rpt.") ¶ 50 (ECF No. 1044-4, at 4-7). He also opined that "a reasonable generic manufacturer in Glenmark's position . . . would request final approval at its first opportunity." J. Clark Rpt. ¶ 108 (ECF No. 1148-2, at 39-40). In the real world, Glenmark did not follow Jon Clark's identified filing strategies, and the FDA approved MSN Labs as an alternative API source in September 2015. Id. ¶ 101 (ECF No. 1148-2, at 37).

c. Todd Clark

Todd Clark considered whether generic firms other than Glenmark would have faced economic incentives to obtain ANDA

[11] An API manufacturer must provide the FDA with information about its facilities, processes, and chemistry, which is contained in a DMF. J. Clark Rpt. ¶¶ 27-28 (ECF No. 1148-2, at 10-11). The DMF is approved as part of the ANDA. Id. ¶ 27.

approval and launch generic ezetimibe sooner if Glenmark had an earlier entry date under the Settlement Agreement. T. Clark Rpt. ¶ 10 (ECF No. 1130-2, at 6); Pls.' SOF, ¶¶ 69-71 (ECF No. 1156, at 43). He will testify that Teva and Sandoz would have launched either (1) at the end of Glenmark's 180-day exclusivity period, if tentatively approved; or (2) when they received tentative FDA approval if Glenmark's exclusivity period had already ended. T. Clark Rpt., ¶ 15 (ECF No. 1130-2, at 7-8).

G. The Present Motion

The matter is now before the court to resolve Merck's and Glenmark's Motions for Summary Judgment on All Claims. (ECF Nos. 1037, 1067). Glenmark argues that Plaintiffs cannot prove that a no-AG agreement was given in exchange for Glenmark's delayed entry, or that Glenmark or other generic manufacturers could have entered the market earlier. Mem. Supp. Glenmark Defs.' Mot. Summ. J. All Claims ("Glenmark Mem.") (ECF No. 1050).[12] Merck also argues that the provision in the Settlement Agreement is not the no-AG provision Plaintiffs allege, and thus cannot be a large and unjustified payment, and that there was no connection between it and Glenmark's generic entry date. Defs. Merck & Co. Mem. L. Supp.

[12] This Report and Recommendation relies upon the parties' sealed memoranda, expert reports, and exhibits. To the extent that the court utilizes facts in disposing of this motion that were originally sealed, the court has determined that the interests of the public outweigh the parties' interests in confidentiality, and the information relied upon is hereby unsealed.

Mot. Summ. J. ("Merck Mem.") (ECF No. 1085). Both Merck and Glenmark argue about the reliability and sufficiency of Plaintiffs' experts' opinions used to rebut the factual claims underpinning the motions.

Plaintiffs opposed both motions for summary judgment in a consolidated brief, arguing that they have sufficient evidence of a no-AG agreement with a value far greater than Defendants' saved litigation costs, and that the large payment provided by this provision caused Glenmark to agree to a later date for entry of its generic that it otherwise would have. Purchasers' Consolidated Opp'n Merck & Glenmark Defs.' Mots. Summ. J. ("Pls.' Opp'n") (ECF No. 1156). Glenmark and Merck replied. Reply Br. Supp. Defs. Merck & Co.'s Mot. Summ. J. ("Merck Reply") (ECF No. 1213); Glenmark Defs.' Reply Br. Supp. Mot. Summ. J. All Claims ("Glenmark Reply") (ECF No. 1195). With the motion fully briefed, the parties appeared by counsel for oral argument on August 17, 2022. On this procedural history and these facts, this report addresses the merits of Defendants' motions for summary judgment. (ECF Nos. 1037, 1067).

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 56 requires the court to grant a motion for summary judgment if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a);

Celotex Corp. v. Catrett, 477 U.S. 317, 322-24 (1986). "A material fact is one that might affect the outcome of the suit under the governing law. A disputed fact presents a genuine issue if the evidence is such that a reasonable jury could return a verdict for the non-moving party." Spriggs v. Diamond Auto Glass, 242 F.3d 179, 183 (4th Cir. 2001) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)) (cleaned up).

The party seeking summary judgment has the initial burden of informing the court of the basis of its motion and identifying materials in the record it believes demonstrates the absence of a genuine dispute of material fact. Fed. R. Civ. P. 56(c); Celotex Corp., 477 U.S. at 322-24. When the moving party has met its burden to show that the evidence is insufficient to support the nonmoving party's case, the burden shifts to the nonmoving party to present specific facts demonstrating that there is a genuine issue for trial. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).

In considering a motion for summary judgment, "the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000); see Anderson, 477 U.S. at 255. "[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine

whether there is a genuine issue for trial." Anderson, 477 U.S. at 249.

III. ANALYSIS

The Sherman Act prohibits agreements that unreasonably restrain trade. 15 U.S.C. § 1. Plaintiffs raise claims under Sections 1 and 2 of the Sherman Act,[13] relying on the Supreme Court's holding in Federal Trade Commission v. Actavis, 570 U.S. 136 (2013). See, e.g., DPPs' Am. Compl. ¶¶ 21, 83 (ECF No. 128, at 11, 29). In Actavis, the Supreme Court held that antitrust laws prohibit reverse payments used to avoid competition from generic drug makers, or so-called "pay for delay" settlement agreements. Actavis, 570 U.S. at 158. Specifically, the Actavis opinion reasoned that courts can infer from the existence of a large reverse payment, not otherwise explained, that the patentee paid the generic drug maker to avoid the risk of patent invalidation and generic competition. Id., at 156. This is because patent settlements generally involve payments from the alleged infringer to the patent holder, whereas pay-for-delay settlements involve the opposite.

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee

[13] Section 1 prohibits conspiring to restrain trade, while Section 2 prohibits conspiring to acquire a monopoly. See Advanced Health-Care Servs. v. Radford Cmty. Hosp., 910 F.2d 139, 144, 147 (4th Cir. 1990).

> and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.

Id., at 157.

Since Actavis, other federal courts have extended this pay-for delay rationale to include not only payments in cash, but also agreements in which the patentholder agrees not to compete with the generic by not producing or licensing an AG. These no-AG provisions, like reverse payments in cash, "may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer." King Drug Co. v. SmithKline Beecham Corp., 791 F.3d 388, 409 (3d Cir. 2015); In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 549-52 (1st Cir. 2016); Impax Labs, Inc. v. Fed. Trade Comm'n., 994 F.3d 484, 494 (5th Cir. 2021) (noting FTC evidence that manufacturers' commitment not to launch an AG increased generics' expected profits by $24.5 million).

In this summary judgment motion,[14] Defendants argue that notwithstanding that reasoning, no reasonable juror could find that Merck paid Glenmark to delay generic entry. They raise several factual claims they say refute the suggestion that their

[14] Merck's and Glenmark's contentions are overlapping. While Defendants generally make similar points, they each also raise different arguments. For the sake of simplicity, arguments are occasionally attributed to all Defendants. Moreover, although Defendants ascribed their arguments to either antitrust liability or antitrust causation and injury, the Court addresses them in connection with the point deemed most material. However, arguments have been considered relevant to both.

settlement included a no-AG agreement of sufficient value to trigger antitrust scrutiny. Defendants also argue that Plaintiffs cannot show that any payment reflected in the Settlement Agreement's restrictions on generic competition was "linked" to Glenmark's delayed generic entry. Finally, they argue Plaintiffs cannot establish they were harmed, as other obstacles would have prevented earlier generic entry by Glenmark and its generic competitors. After reviewing the record, and resolving disputes of material fact in Plaintiffs' favor, I conclude that reasonable jurors could find for Plaintiffs on all these issues, and thus, this report recommends the court deny summary judgment.

A. Plaintiffs Have Established a Disputes of Material Fact on Anti-Trust Liability, or the Existence of a Large and Unjustified Payment, under Actavis.

To survive summary judgment, there must be a genuine dispute of material fact about whether Merck made an "improper reverse payment[] to induce [Glenmark] to delay its generic launch." In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 264 (D. Mass. 2014). The only cash payment in the Settlement Agreement was the $9 million Merck paid to reimburse Glenmark's documented litigation costs. Merck SOF ¶ 35 (ECF No. 1085, at 18-19). Plaintiffs thus characterize the asserted no-AG Agreement in §§ 5.3 and 1.14 of the Settlement Agreement as a "large and unjustified" payment under Actavis. Pls.' Opp'n (ECF No. 1156, at 11). Defendants contend that the cited language is not a no-AG

Agreement because it permitted competition by Merck with another branded drug. They also contend the provision was not given to eliminate the risk of competition, or in the other words, in exchange for Glenmark's agreement to delay generic entry. Glenmark Mem. (ECF No. 1050, at 30); Merck Mem. (ECF No. 1085, at 27).

However, as discussed below, applying reasonable inferences in favor of Plaintiffs, jurors could find the requisite elements of both Sherman Act claims under Actavis. Plaintiffs have established triable issues regarding the existence of a no-AG agreement; the value of that agreement; and the connection between that agreement and Merck's avoidance of at least some risk of generic competition. Under Rule 56, this is sufficient to allow Plaintiffs' claims to proceed to trial.

1. There is a dispute of material fact regarding whether the Settlement Agreement contained a no-AG Provision of the type Plaintiffs allege.

While Defendants cannot reasonably dispute that the Settlement Agreement restricts competition with Glenmark's generic during exclusivity, the parties vigorously debate the nature of the restrictions. Merck argues that Plaintiffs cannot "label the provision a no-AG agreement that prohibited Merck from selling any authorized generic" because it was allegedly only a "limited exclusive license" reserving to Merck the ability to market a so-

called branded generic.[15] Merck Mem. (ECF No. 1085, at 32) (emphasis in original). Merck relies on the license provision's exclusion of drugs "sold under the trademark Zetia® or another trademark or trade name" of Merck. Sett. Agr. § 1.14 (ECF No. 398-21, at 6) (emphasis added). Plaintiffs argue that the Settlement Agreement "prohibited Merck from selling a Zetia AG whether under a generic chemical name or a brand name." Pls.' Opp'n (ECF No. 1156, at 61). They also contend that even if Merck could sell its branded generic, it had no intention to, and would not have, and thus the license operated identically to a no-AG provision. As discussed below, Plaintiffs have established disputes of material fact regarding whether the provision constituted a no-AG agreement.

a. There is a dispute of material fact about whether the provision in the Settlement Agreement constitutes a no-AG agreement.

Merck argues that the Settlement Agreement does not contain a no-AG Agreement as a matter of contract interpretation. Merck Reply (ECF No. 1213, at 24-28); see also Merck Mem. (ECF No. 1085, at 30). It argues that, because the contested provision carves

[15] As used throughout this R. & R., "branded generic" is a pharmaceutical product conforming to Merck's definition, that is, a generic that is sold under some "trademark or trade name" of Merck that is not Zetia. See Sett. Agr. § 1.14 (ECF No. 398-21, at 6). The generic name, ezetimibe, by definition is not a "trademark or trade name" of Merck. See, Daphne E. Smith Marsh, Overview of Generic Drugs and Drug Naming, Merck Manual Consumer Version (Aug. 2017), www.merckmanuals.com/home/drugs/brand-name-and-generic-drugs/overview-of-generic-drug-and-drug-naming.

out branded generics, reasonable jurors applying its plain meaning could not conclude it is a no-AG agreement. Merck Reply (ECF No. 1213, at 25). Plaintiffs respond with extensive evidence that Glenmark sought a no-AG agreement during negotiations, and that both Merck and Glenmark made post-settlement decisions reflecting Defendants' mutual understanding that the settlement restricted Merck's ability to launch an AG. Pls.' Opp'n (ECF No. 1156, at 49-61). A reasonable juror could rely on this evidence of the Agreement's restrictions on generic competition and Plaintiffs' other evidence to find that the provisions in question constitute a no-AG agreement.

The Settlement Agreement is construed according to New Jersey law. Sett. Agr. ¶ 10.3 (ECF No. 398-1, at 23). New Jersey applies the "familiar rules of contract interpretation," which require courts to "enforce the agreement as written" if "the intent of the parties is plain and the language is clear and unambiguous . . . unless doing so would lead to an absurd result." Barila v. Bd. of Educ., 230 A.3d 243, 255 (N.J. 2020) (quoting citations omitted). However, ambiguous contractual terms permit the "broad use of extrinsic evidence to achieve the ultimate goal of discovering the intent of the parties." Conway v. 287 Corp. Ctr. Assoc., 901 A.2d 341, 347 (N.J. 2006). To support its plain meaning argument, Merck leans heavily on the court's order on the motion to dismiss, which observed that "[t]he parties and the court agree that the

Settlement Agreement's definition of 'Generic Ezetimibe' clearly permits Merck to sell a branded product . . . ." (ECF No. 489, at 15). However, the court also found that "the Settlement Agreement did not allow Merck to sell a generic product, including an AG," and that the definition of generic ezetimibe [in the Settlement Agreement] "can plausibly be read as a no-AG agreement." Id. at 20. Thus -- even with the carveout for branded generics -- the provision could constitute a no-AG agreement. Moreover, the Settlement Agreement language is not so clear that summary judgment could be awarded to either party based on the textual argument alone.

Plaintiffs argue that the court can consider extrinsic evidence on the term's meaning, either because the contract is ambiguous, or because this is an antitrust case. Pls.' Opp'n (ECF No. 1156, at 58-59). The Eighth Circuit has observed that "aspiring monopolists" are probably not "foolish enough to reduce their entire anticompetitive agreement to writing," but would instead draft a contract without the illegal terms. Wholesale Grocery Prods. Antitrust Litig., 752 F.3d 728, 734 (8th Cir. 2014). Defendants state this case "holds only that parties to a Sherman Act conspiracy could have reached an oral or implicit agreement that went beyond the written agreement," but "Plaintiffs here have not pled or proven any agreement other than the settlement agreement." Merck Reply (ECF No. 1213, at 26). However,

Plaintiffs have repeatedly contended that the no-AG agreement prevented Merck from selling an AG during Glenmark's exclusivity period. They have also argued that the drafting history suggests the parties intended to disguise restrictions on AG competition by recasting the defined term "Authorized Generic" as a component of "Generic Ezetimibe" and providing Glenmark with an exclusive license over both. This is adequate to permit reliance on their extrinsic evidence. And the evidence Plaintiffs offer amply supports their view that the Settlement Agreement precluded generic competition from Merck during Glenmark's first filer exclusivity.

First, it's clear that Glenmark sought a no-AG agreement during negotiations. Soni emailed Matukaitis about a no-AG, later clarifying that it was for Glenmark's exclusivity period.[16] Glenmark Ex. 19 (ECF No. 1039-19, at 2); Merck Ex. 36 (ECF No. 1082-11, at 2). The drafting history also corroborates Plaintiffs'

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[16] Soni's notes are ambiguous about Merck's response to this term. According to those notes, Merck responded on March 1 with two months early entry and "No AG for Zetia : NO," (ECF No. 1082-11, at 2).

Plaintiffs assert that the NO after the colon "corresponds to Glenmark's additional request for the Vytorin AG, not the Zetia no-AG." Pls.' Opp'n (ECF No. 1156, at 16-17). Defendants contend that the NO refers to Zetia. Merck Reply (ECF No. 1213, at 12). Considering that Soni's notes on an earlier demand had been styled as "No AG Zeta/AG for Vytorin," (ECF No. 1082-11, at 2), with the two products listed together and separated by a slash, the argument that any words after the colon refer to the second Vytorin product is not a reading no reasonable juror could credit. This is especially so given the extensive evidence after settlement that Glenmark believed it would have no generic competition from Merck.

allegations that the Settlement Agreement would prevent Merck from launching an AG. An early draft contained a definition of "Authorized Generic" which compares with Plaintiffs' claimed definition – i.e. sold under the Zetia NDA, but not under the original brand or another trademark or tradename of Merck. This language was later incorporated into the description of "Generic Ezetimibe" which the Settlement Agreement exclusively licensed to Glenmark during its 180-day period of exclusivity. While deposition testimony from negotiators asserts that Merck never intended to give Glenmark a no-AG agreement, see, e.g., Matukaitis Dep. 206:8-14 (ECF No. 1082-9, at 26), resolving conflicts in the evidence in Plaintiffs' favor, reasonable jurors could conclude that a no-AG Agreement was one of the terms the parties considered during negotiations, and that they intended the language they eventually agreed on to restrict Merck's ability to compete with its own generic version of Zetia.

In addition to the negotiation history, the Parties' post-settlement decisions strongly corroborate Plaintiffs' claims of a no-AG provision. Glenmark sought investments and made revenue modeling decisions based on its explicit understanding that it would face no generic competition during its first filer exclusivity. Pls.' SOF ¶¶ 14-17 (ECF No. 1156, at 27-28). The company also received the Greenberg-Traurig legal opinion expressly concluding that the Settlement Agreement contained a no-

AG provision, Pls.' Ex. 184 (ECF No. 1157-23, at 4), and Merck based its own aborted generic launch decisions on the same assumption, Pls.' Ex. 111 (ECF No. 1152-14, at 15). The 2016 dispute over the time period covered by the generic restrictions supports Plaintiffs' view that the Settlement Agreement's exclusivity language barred all generic competition from Merck. The fact that the company attempted to launch an unbranded generic four months after entry of the Glenmark generic -- instead of the branded generic that they claim to have reserved in the text of § 1.14 -- is probative of the type of provision they considered it to be. There is therefore sufficient evidence in the summary judgment record from which reasonable jurors could conclude Merck agreed not to launch any AG.

b. There is a dispute of material fact about whether a branded generic would have been a commercially reasonable product for Merck to market.

Even if Merck could market a branded generic under the Settlement Agreement, Plaintiffs argue that the carveout permitting one is essentially valueless because a branded generic "is not something that a brand company would consider marketing, and the evidence strongly suggests that Merck would not have done so." Pls.' Opp'n (ECF No. 1156, at 61). Thus, Plaintiffs argue that Merck would not have utilized the carveout by attempting to launch a second brand, and that Glenmark assumed it would not do so. Plaintiffs should be permitted to prove this at trial.

Separate from their disagreements over the language in the Defendants' Settlement Agreement, the parties dispute whether AGs are understood within the industry to include branded generics. Merck contends that the "legal definition" of an AG includes branded generics. Merck Mem. (ECF No. 1085, at 30). Indeed, the Federal Food, Drug, & Cosmetic Act defines an AG as including a drug sold "under a different . . . trade name, or trade mark than the listed drug," which Merck contends includes branded generics. 21 U.S.C. § 355(t)(3)(B). The FTC also explains that "AGs do not bear the brand-name or trademark of the brand-name drug or manufacturer," Pls.' Ex. 212 (ECF No. 1158-20, at 4), which both parties contend is consistent with their interpretation, Pls.' Opp'n (ECF No. 1156, at 62 & n.271); Merck Mem. (ECF No. 1085, at 30).

Despite this statutory language, Plaintiffs' evidence suggests that brand manufacturers infrequently launch such products. Only 3% of generics are branded, "[v]irtually all" of which are oral contraceptives or used to balance hormones. Pls.' SOF ¶ 35 (ECF No. 1156-33, at 33); id. at 62. As Zetia is a cholesterol medication, it does not obviously fall into this category. Plaintiffs' expert Meredith Rosenthal also testified why -- even if possible - branded generics are generally not marketed within the industry. See Rosenthal Dep. 178:3-187:11 (ECF No. 1154-4, at 7-16). Rosenthal testified that she could not think of

any examples of pharmaceutical companies launching branded generics or "think of any sound economic reason to do" so. Id. 187:1-13 (ECF No. 1154-4, at 16). McGuire also testified that he had no experience with this. McGuire Dep. 67:7-68:9 (ECF No. 1152-9, at 3-4) ("I've never encountered that.").

Plaintiffs' evidence is sufficient for reasonable jurors to conclude that Merck would not have launched such a product, even if permitted by the Settlement Agreement. Merck launched an unbranded AG for every one of its blockbuster drugs that lost patent exclusivity between 2006 and 2017, except for Zetia. Pls.' SOF ¶ 37 (ECF No. 1156, at 34) (referencing products with annual sales above $200 million). And Merck has never sold a second branded product to compete with generics after losing exclusivity. Id. ¶ 34 (ECF No. 1156, at 33). Thus, if Merck had decided to launch a branded generic to compete with Glenmark's generic ezetimibe product, it would be the first of its kind for the company. These facts are not "immaterial" as Merck argues. Merck Reply (ECF No. 1213, at 16) ("That Merck launched AGs of some other drugs does not bear on its motion."). Merck's failure to launch a branded generic ever before, and its consistent history of generic competition using the generic name after losing

exclusivity, are probative of how both companies valued the alleged carveout for a branded generic when it was drafted in May 2010.[17]

Merck argues that "[w]hether Merck ultimately contemplated launching a branded generic is irrelevant to the value of the provision" because the Sherman Act only penalizes the agreement. Merck Mem. (ECF No. 1085, at 33). It is undisputed that Plaintiffs' action relies on the agreement Defendants made in May 2010, not whether Merck "just later decided not to make" a branded generic after negotiating for it. See Mot. Dismiss H'r Tr. 68:9-18 (ECF No. 233). But if Plaintiffs can establish at trial that Merck reserved for itself a right that, even during settlement negotiations, it never intended to exercise -- a jury could find that Merck's ability to compete through some branded generic without using the generic ezetimibe moniker would not diminish the value of the no-AG agreement to Glenmark. Plaintiffs' evidence is sufficient to create a triable issue on this point.

2. There is a dispute of material fact about the value of the no-AG Agreement.

The central issue regarding the no-AG Agreement is not the precise sematic parameters of that agreement but its value to Merck and Glenmark. Merck contends that Plaintiffs' experts "fail to value the provision to which the parties actually agreed," making

[17] While some of Plaintiffs' evidence concerns dates after May 2010, Merck's failure to launch a branded generic (and continuing to launch AGs) post-2010 could show a jury that Merck was not changing strategy.

their evidence of its value "speculative and unreliable." Merck Mem. (ECF No. 1085, at 32); see also Glenmark Mem. (ECF No. 1050, at 26 n.8). Defendants again focus on the branded generic carveout, which they allege permitted Merck to compete against Glenmark's generic ezetimibe during the exclusivity period without violating the Settlement Agreement in ways a no-AG agreement without the carveout would not. The value of the no-AG agreement is central because it represents the large and unjustified payment which must support an inference that the patentholder "likely seeks to prevent the risk of competition." Actavis, 570 U.S. at 157. Plaintiffs' evidence would permit reasonable jurors to conclude that Merck and Glenmark both considered the no-AG Agreement sufficiently valuable.

a. Valuation of the no-AG Agreement

Plaintiffs must establish that the no-AG agreement was valuable to both Merck and Glenmark. For generic manufacturers like Glenmark, no-AG agreements can be very valuable because they assign "a 180-day monopoly over the generic market." King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388, 407 (3d Cir. 2015). But "[t]he first-filing generic cannot capture this value by early entry alone. It can only hope to obtain this value with the brand's self-restraint . . . ." Id. Because Glenmark was the ANDA first filer for Zetia, Glenmark would expect to face competition in the generic market from Merck's AG,

substantially reducing its first-filer profits. Id., at 404 (citing FTC evidence that no-AG agreement "would have been worth hundreds of millions" to generic first filer). See, Impax Labs, Inc., 994 F.3d at 494 (5th Cir. 2021) (citing FTC evidence that no-AG agreement increased generic's expected profit by $24.5 million). Even if Glenmark won the litigation, Glenmark faced a risk that Merck would launch an AG during its exclusivity period. In fact, when Merck planned an AG launch in April 2017, Glenmark threatened suit. Pls.' Ex. 100 (ECF No. 1152-3). Thus, a settlement agreement with a no-AG agreement would give Glenmark terms it could not have reached through litigation. Cf. In re Androgel Antitrust Litig. (No. II), No. 1:09-CV-955-TWT, 2018 WL 2984873, at *12 (N.D. Ga. June 14, 2018) (finding parties negotiated to prevent competition when the settlement agreement "left them better off than any party would have been had the Generics won the patent litigation").

No-AG agreements also generally represent substantial financial sacrifice for brand manufacturers. King Drug, 791 F.3d at 405 ("[A] brand's commitment not to produce an authorized generic means it must give up the valuable right to capture profits in the two-tiered market"). Anti-trust law as interpreted in Actavis prohibits using the "no-AG agreement [to] transfer[] the profits the patentee would have made from its authorized generic to the settling generic." Id. Such restrictions fit the pay for

delay pattern because "the source of the benefit to the claimed infringer is something costly to the patentee." King Drug Co., 791 F.3d at 405.

Plaintiffs rely on experts McGuire and Leffler to value the no-AG Agreement in May 2010. McGuire and Leffler examined two potential periods when the no-AG Agreement would apply -- either the full 180-days of Glenmark's exclusivity, or for the 135 days prior to April 26, 2017, when Merck had asserted in 2016 that the no-AG agreement ended.[18] See McGuire Rpt. ¶ 105 (ECF No. 1130-8, at 55); Leffler Rpt. ¶ 68 (ECF No. 1130-4, at 43-44). They estimated that Merck sacrificed between $25.5[19] and $160[20] million by granting Glenmark a Zetia no-AG agreement. They also estimated

[18] The dispute over the end date for Glenmark's exclusive generic license relates to language in the licensing terms suggesting it lasted until Merck's rights under the patent expired, which Merck asserted was approximately 45 days before Glenmark's first-filer exclusivity period ended. For purposes of this motion, it's not necessary to determine which period is correct.

[19] McGuire estimated that Merck would have lost at least $25.5 million during the shorter 135-day timeframe, but also estimated it could have been as much as $49.3 million. McGuire Rpt. ¶ 102 (ECF No. 1130-8, at 53). Leffler estimated $62.2 million for the same timeframe. Leffler Rpt. ¶ 71 n.84 (ECF No. 1130-4, at 47).

[20] Leffler found a cost for Merck of about $160 million during the full 180 days, Leffler Rpt. ¶ 68 (ECF No. 1130-4, at 43-44), but also estimated it could have been as low as $89 million, id. ¶ 71 (ECF No. 1130-4, at 46-47). McGuire found a range of $33.9-$65.7 million for the same timeframe. McGuire Rpt. ¶ 105 (ECF No. 1130-8, at 55).

that Glenmark stood to gain between $62.3[21] to $125[22] million by marketing a Zetia generic without competition from a Merck AG. Thus, McGuire and Leffler estimate that a Zetia AG was worth at least $25.5 million but could have been markedly more valuable.

Defendants previously sought to exclude McGuire and Leffler's valuations entirely in their separate motion against the experts, (ECF No. 1048), which was denied, (ECF No. 1649). I do not address these reiterated arguments in detail here. However, Merck insists that, notwithstanding their testimony, Plaintiffs' evidence is insufficient to survive summary judgment because their experts have not valued the limited exclusive license with the carveout for a branded generic. They argue this failure to consider a branded generic leaves Plaintiffs with no evidence that the generic restrictions "had any value at all" to Defendants. Merck Mem. (ECF No. 1085, at 33). This is not correct. As set out in more detail in my opinion denying Defendants' motion to exclude McGuire and Leffler, Plaintiffs have articulated their version of the facts, and supported it with citations to admissible evidence in the summary judgment record. Opinion & Order, at 17-20 (ECF No. 1649). Their experts have valued the provision in concert with

[21] McGuire calculated $62.3 million. McGuire Rpt. ¶ 112 (ECF No. 1130-8, at 58-59).

[22] Leffler calculated $125 million. Leffler Rpt. ¶ 70 (ECF No. 1130-4, at 47).

that version. At least on summary judgment, Plaintiffs' case does not fail just because they have not provided a different valuation that comports with Defendants' version of the facts.[23]

b. Comparison to litigation expenses and other reasonable settlement costs.

Of course, a large payment allows an inference of anticompetitive intent only when it is "unjustified" by the circumstances. Actavis, 570 U.S. at 158. The Supreme Court identified factors to consider when evaluating whether a settlement payment was justified:

> the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.

Id. at 159. Thus, when payments are larger than reasonably necessary to address settlement concerns, plaintiffs "satisf[y] their burden in showing that the settlements violated the antitrust laws." In re Androgel Antitrust Litig. (No. II), No. 09-CV-955, 2018 WL 2984873, at *9 (N.D. Ga. June 14, 2018). Plaintiffs have

[23] In this briefing and associated motions, Defendants occasionally represent that, in 2010, Congress was considering outlawing authorized generics during the exclusivity period as anticompetitive. Merck Mem. (ECF No. 1085, at 35) (citing S.3695 (ECF No. 1084-15); H.R.5993 (ECF No. 1084-16)); see also Defs.' Reply (ECF No. 1201, at 23). However, any arguments that might weaken the analogy between a 2016 and 2010 valuation go to the weight of the expert testimony, not admissibility. Cf. E. Tenn. Nat. Gas Co. v. 7.74 Acres, 228 F. App'x 323, 327-29 (4th Cir. 2007) (affirming admission over objections that experts "did not use truly 'comparable' sales to determine the [property] value").

established a dispute of material fact about whether the payment exceeded Defendants' avoided future litigation costs. Further, the amount Merck paid Glenmark as compensation for expended legal costs is properly considered as part of the reverse payment amount.

i. Merck and Glenmark avoided future litigation expenses.

Plaintiffs argue that the no-AG agreement was more valuable than the litigation expenses. Pls.' Opp'n (ECF No. 1156, at 64-65). Using the legal fees from the Mylan trial, Merck claims that it saved approximately $7.1 million by settling with Glenmark. Jakob Dep. 32:16-21 (ECF No. 1151-11, at 5). In contrast, Hrubiec opines that Merck and Glenmark each saved approximately $4.5-5 million in legal expenses. Hrubiec Rpt. ¶ 314 (ECF No. 1083-18, at 139).

Merck argues that there is an Actavis "safe harbor" for certain attorney's fees amounts, which the attorney fee payments in this case exceed by only $2-4 million. Merck Mem. (ECF No. 1085, at 36-37). In another case the FTC agreed to stipulate that up to $7 million in avoided attorney's fees would not constitute a reverse payment. FTC v. Cephalon, Inc., No. 2:08-cv-2141, 2015 WL 4931442, at *2 (E.D. Pa. June 17, 2015). But in this case the attorney's fees payment was expressly denominated as reimbursement for Glenmark's attorney's fees already incurred, not the avoided future litigation expenses of Merck. See, id.

ii. Merck's $9 million payment for Glenmark's expended litigation expenses.

Merck paid Glenmark $9 million for litigation costs "incurred in the preparation for and prosecution and defense" of the case.[24] Sett. Agr. § 7.3 (ECF No. 398-21, at 18); see also Merck SOF ¶ 35 (ECF No. 1085, at 18-19). Plaintiffs contend that this $9 million should be considered part of the unjustified payment. See Pls.' Opp'n (ECF No. 1156, at 64-65 & n.281). Defendants argue that expended litigation costs are "immune under Actavis," and the court should not consider it. Merck Reply (ECF No. 1213, at 17); see also Merck Mem. (ECF No. 1085, at 36-37); Glenmark Mem. (ECF No. 1050, at 17 n.4). Plaintiffs' evidence creates a material dispute about whether the $9 million should be included as part of the unjustified payment.

Payments that "reflect[] traditional settlement considerations" are justified. Actavis, 570 U.S. at 156. Settlements frequently provide for incurred legal expenses, but these are ordinarily recovered by the Plaintiff—not, as here—by a settling Defendant like Glenmark. Although Actavis mentioned only avoided litigation costs, the Supreme Court provided examples, not an exhaustive list of the type of considerations. Id. The Eastern

[24] The Settlement Agreement required Glenmark to provide Merck with reasonable documentation of the legal fees. Sett. Agr. ¶ 7.3 (ECF No. 398-21, at 18). Plaintiffs imply that Glenmark's costs may not have exceeded the full $9 million. See Pls.' Opp'n (ECF No. 1156, at 64).

District of Pennsylvania has observed that in evaluating reimbursement of incurred fees as part of a reverse payment settlement the whole payment must be considered together:

> I . . . disagree . . . that only the unexplained portion of a reverse payment should be considered in assessing whether a reverse payment is large. . . . Defendants, not Plaintiffs, bear the burden of explaining the payments. Whether or not the payment constitutes "fair value for services" or some other legitimate justification will be in contention in nearly every case, with plaintiffs arguing that most, if it not all, of the payment is mere pretext for a payment for delay. Therefore, I find that the entirety of the reverse payment should be considered in determining whether the payment is large under Actavis.

King Drug Co. of Florence v. Cephalon, Inc., 88 F. Supp. 3d 402, 418 (E.D. Pa. 2015). A settlement agreement must be "viewed holistically" to determine whether "it effects a large and unexplained net transfer of value" between parties. In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 243 (D. Conn. 2015).

Defendants criticize Plaintiffs' experts for adopting this approach and not evaluating the stand-alone impact of the $9 million payment. McGuire and Leffler considered the payment along with the value they ascribe to the no-AG agreement. See, e.g., McGuire Rpt. ¶ 5 (ECF No. 1130-8, at 6); Leffler Rpt. ¶¶ 70-71 (ECF No. 1130-4, at 45-47). However, the experts did not independently analyze the effects of the $9 million payment in connection with the "incurred legal expenses" it purported to reimburse. See, e.g., McGuire Dep. 335:3-10 (1087-1, at 108)

(agreeing it "sound[ed] fair" that he had "not undertaken an economic analysis to determine the competitive effects of the $9 million payment by Merck to Glenmark without the alleged no AG term"). They were not required to do so. Because the $9 million moved from Merck, the patentholder, to Glenmark, the alleged infringer, reasonable jurors could find it was part of a reverse payment, even if it partly or entirely reimbursed for expenses Glenmark had already incurred.

3. There is a dispute of material fact about the connection between Glenmark's generic entry date and the no-AG Provision.

For an agreement to be unlawful, Actavis requires that it aim "to prevent the risk of competition." Actavis, 570 U.S. at 157. During the Glenmark litigation, Merck faced competitive risk: namely, that if Merck's RE'721 patent was invalidated, the price of branded Zetia would dramatically decrease long before the patent was set to expire because of competition with Glenmark's generic ezetimibe and eventually with other generic manufacturers' products. Obtaining dismissal of Glenmark's validity challenge and a fixed generic entry date avoided this risk for over six years during which Merck would not face generic competition from Glenmark. And Plaintiffs argue that Merck paid Glenmark to do so through the no-AG provision. Pls.' Opp'n (ECF No. 1156, at 11). However, Defendants argue that -- even if the Settlement Agreement contained a no-AG agreement -- Plaintiffs have not proven that it

was given to avoid Merck's competitive risk, and could not have done so in any event. Glenmark Mem. (ECF No. 1050, at 32); Merck Mem. (ECF No. 1085, at 40). For the purposes of summary judgment, Plaintiffs have provided sufficient evidence for jurors to conclude that it was, and that it did.

a. Actavis does not require explicit evidence of a quid pro quo exchange to establish anticompetitive effects.

Both Sherman Act claims in this case "require the same threshold showing – the existence of an agreement to restrain trade." In re Androgel Antitrust Litig. (No. II), No. 1:09-md-2084, 2018 WL 2984873, at *7 (N.D. Ga. June 14, 2018). The Settlement Agreement will satisfy this requirement if it "embodies an agreement to unlawfully restrain trade." Id. All parties agree that to succeed on its claims, Plaintiffs must prove that Glenmark's delay was given in exchange for Merck's no-AG agreement: that is Actavis. See Pls.' Opp'n (ECF No. 1156, at 11). But Defendants argue that Plaintiffs must prove the explicit link to defeat summary judgment. See, e.g., Glenmark Reply (ECF No. 1195, at 7) (arguing "[t]he existence of an exchange is at the heart of the[se] types of reverse payments"). Merck claims that, as "a gating issue," antitrust plaintiffs must establish that a large and unjustified payment was made in exchange for delay before the rule of reason applies. Merck Mem. (ECF No. 1085, at 28 & n.3). Glenmark also argues that Actavis created a "threshold requirement

before rule of reason scrutiny is triggered: (1) a large and unjustified payment (2) made in exchange for a delayed entry date." Glenmark Mem. (ECF No. 1050, at 9).

Plaintiffs argue that Actavis did not establish "a special burden the purchasers must satisfy before they have an opportunity to prove their case under the rule of reason." Pls.' Opp'n (ECF No. 1156, at 44). In their view, the Actavis inference essentially becomes the first stage of the rule-of-reason analysis. See id. at 47 ("[A]s part of the rule of reason analysis, the purchasers must prove a 'payment to prevent the risk of competition.'" (quoting In re Loestrin 24 Fe Antitrust Litig., 433 F. Supp. 3d 274, 316, 320 (D.R.I. 2019)).

The traditional rule of reason is a burden-shifting framework for analyzing an agreement's anticompetitive effects, see Va. Vermiculite, Ltd. v. W.R. Grace & Co.- Conn., 108 F. Supp. 2d 549, 575 (W.D. Va. 2000), which "courts analyzing reverse payment agreements have consistently applied," In re Zetia (Ezetimibe) Antitrust Litig., No. 2:18-md-2836, 2019 WL 1397228, at *20 (E.D. Va. Feb. 6, 2019), R. & R. adopted as modified by 400 F. Supp. 3d 418 (E.D. Va. Aug. 9, 2019).

Actavis did not change the rule of reason analysis. See Actavis, 570 U.S. at 159 ("These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases."); id. at 160 ("We therefore leave to the lower courts the

structuring of the present rule-of-reason antitrust litigation."). However, the reasoning in Actavis is that a patentee cannot "leverage[] some part of its patent power . . . to cause anticompetitive harm -- namely, elimination of the risk of competition." King Drug Co., 791 F.3d at 406; see also Loestrin, 433 F. Supp. 3d at 318 ("[T]he reverse payment macrocosm concerns whether the patentee sought to induce a generic challenger to abandon its claim for a share of the monopoly profits." (citations omitted)). Thus, the "gating issue" under Actavis is proof of the Agreement's affect on competition. And, as explained in that opinion, this requires sufficient evidence that the agreement included a payment to the generic challenger, and avoided the risk of competition from the settling generic. Once that is established, the agreement must be analyzed under the ordinary rule of reason approach. See Loestrin, 45 F. Supp. 3d 180, 189 (D.R.I. 2014), rev'd on different grounds, 814 F.3d 538 (1st Cir. 2016).

The parties' dispute about these "threshold issues" is more than an academic debate about "precisely when the Court should consider" the Actavis inference -- it concerns the kind of evidence necessary to use the inference. Merck Reply (ECF No. 1213, at 20) (emphasis in original). Defendants suggest that Plaintiffs must produce a smoking gun, the actual handshake, or a documented *quid pro quo* promise of a delay given in exchange for the payment, as

a threshold matter. But Actavis did not hold that evidence of the exchange must be so explicit. See generally Actavis, 570 U.S. 136 (failing to discuss direct evidence). The Actavis inference is simply one part of the ordinary rule-of-reason inquiry which holds that when an agreement involves a patentholders exercise of monopoly power to avoid the risk of competition – "a large and otherwise unexplained payment, combined with delayed entry, supports a reasonable inference of harm to consumers from lessened competition." Aaron Edlin et al., The Actavis Inference: Theory & Practice, 67 Rutgers U. L. Rev. 585, 585 (2015). As set forth above, Plaintiffs' evidence on summary judgment would permit jurors to conclude the Settlement Agreement avoided the risk of competition. They obtained dismissal of Glenmark's validity challenge, and its agreement not to market a generic for over six years. They also have sufficient evidence that as consideration for this agreement Merck gave up "the valuable right" to compete with its own AG. King Drug, 791 F.3d at 405. If Plaintiffs also establish that, this no-AG provision was a large and otherwise unjustified payment, then a jury can infer from its size and lack of justification that the "payment's objective is to maintain supracompetitive prices to be shared . . . rather than face what might have been a competitive market." Actavis, 570 U.S. at 157. Indeed, if Plaintiffs were required to produce explicit evidence

of an unlawful agreement before invoking Actavis, there would be no need for an inference at all.

Glenmark argues that Actavis did not hold that "evidence of a large payment, standing alone, was sufficient to prove the required exchange of a payment by the brand in return for the generic's agreement to drop its patent challenge." Glenmark Mem. (ECF No. 1050, at 26 n.7). This is correct -- but Plaintiffs are not the parties seeking summary judgment. They have not asked the court to declare Defendants liable based solely on those facts. To defeat summary judgment on Defendants' claim that they did not violate antitrust prohibitions, Plaintiffs need only produce sufficient evidence for a reasonable juror to find that they met their prima facie case. In re Androgel Antitrust Litig. (No. II), No. 1:09-CV-955-TWT, 2018 WL 2984873, at *12 (N.D. Ga. June 14, 2018). They do not need incontrovertible proof of an exchange. See Samson v. Wells Fargo Bank, N.A., 777 F. App'x 881, 883 n.1 (9th Cir. 2019) ("[A] smoking gun is not needed to overcome a motion for summary judgment." (quoting Henderson v. United Student Aid Funds, Inc., 918 F.3d 1068, 1082 (9th Cir. 2019) (Bybee, J., dissenting) (cleaned up)).

b. A reasonable juror could find that the Settlement Agreement effected an exchange to delay competition.

As discussed above, Plaintiffs do not need explicit evidence that Merck and Glenmark linked the two Settlement Agreement

provisions to prove their case. Evidence that the no-AG agreement existed and was highly valued is sufficient to utilize the Actavis inference. Furthermore, Plaintiffs' argument that the no-AG agreement compensated Glenmark for generic delay is amply supported by their causation arguments, which are discussed in more detail below.[25] However, a few more points on the violation require attention.

First, Defendants argue that the Actavis inference cannot be used "where the facts conclusively prove that the alleged payment did not (and could not) have that effect." Merck Mem. (ECF No. 1085, at 38). Defendants rely on deposition testimony to show that "there was no tradeoff - indeed, there was no link whatsoever -- between the entry date and the claimed no-AG provision." Glenmark Mem. (ECF No. 1050, at 30). But there is no dispute that the Settlement Agreement resulted in Glenmark dropping its claims of invalidity and agreeing not to launch its ezetimibe generic until December 2016. And as discussed above, the negotiators' testimony about the existence of a no-AG provision is inconsistent

[25] Glenmark argues that "the question of what alternative entry dates the parties may have reached for purposes of causation is distinct from the threshold requirement under Actavis that there be an exchange that induced the generic's decision to drop its patent challenge." Glenmark Mem. (ECF No. 1050, at 30). While the court agrees that any opinions on distinct alternative entry dates is appropriately a causation issue, in establishing these calculations, experts simultaneously opine on the strength of the connection between the no-AG agreement and the date of generic entry.

with their contemporaneous written record, and subsequent actions. Pls.' Opp'n (ECF No. 1156, at 60-61). Moreover, regardless of any perceived inconsistencies in the negotiators' recollections (and without making credibility determinations), I observe that the cited testimony is insufficient on summary judgment to conclusively refute a link between the provisions.

Second, Plaintiffs' experts McGuire and Leffler did not—as Defendants argue—concede that there was no exchange. Pls.' Opp'n (ECF No. 1156, at 65). Glenmark characterized the testimony of McGuire and Leffler as "confirm[ing] the absence of any question of material fact" on this issue. Glenmark Mem. (ECF No. 1050, at 33). But all McGuire and Leffler testified was that they had not "seen . . . the communication that indicated an exchange, an explicit exchange between the two" in this case. McGuire Dep. 109:1-3 (ECF No. 1039-23, at 8); see also Leffler Dep. 269:19-271:8 (ECF No. 1082-20, at 62-64). In answering Defendants' questions about the link, McGuire also referenced

> a literature which is both . . . law and economics, and economic literature, that does link the no AG with a date. And if that's something that I took account of, and . . . using my experience and the papers that I refer to and the logic they contain, that's how to understand the relationship between a no AG clause and the date.

McGuire Dep. 109:7-17 (ECF No. 1039-23, at 8). McGuire also testified that "the settlement agreement itself" was evidence of an exchange. Id. 93:13-16 (ECF No. 1039-23, at 6). Leffler

explained that settlement discussions provide "a collection of value," which is "like a quid pro quo . . . ." Leffler Dep. 270:3-16 (ECF No. 1082-20, at 63). Thus, although the experts did not testify to viewing some specific document explicitly confirming the exchange, their testimony regarding its value can reasonably support a jury's inference that the Agreement included a reverse payment and avoided the risk of competition – this is the only threshold issue to be addressed before applying the rule of reason analysis to assess the agreement's anti-competitive effects. See, Androgel, 2018 WL 2984873, at *8 ("avoiding even the possibility of competition, however, small, is itself an antitrust violation") (citing Actavis, 570 U.S. at 157).

c. Mylan Litigation

Merck also argues that the Settlement Agreement did not prevent or delay generic competition because it faced the same risk of an invalidated patent from Mylan. Merck Reply (ECF No. 1213, at 21). Indeed, the Glenmark and Mylan litigations are related in a way not contemplated in Actavis. There, the Court acknowledged that reverse payments to ANDA first filers (like Glenmark) have heightened antitrust concerns because those are the "most motivated" patent challengers. Actavis, 570 U.S. at 155 (quoting citation omitted). However, in this case, both Glenmark and Mylan were first filers for different pharmaceutical products (Zetia and Vytorin) that were both protected by the same RE'721

Patent. Thus, Merck argues that Mylan "was at least as motived as Glenmark to challenge" the patent. Merck Mem. (ECF No. 1085, at 26). Merck argues the pending Mylan litigation had two relevant effects: (1) Defendants could not have avoided competition, because Mylan sought to invalidate the same patent; and (2) that the Settlement Agreement did not delay competition, in fact, because the Mylan litigation held the patent valid. Id. at 26-27. As Merck concedes, no other court has addressed the relevance of a second pending patent litigation case precisely like this. See id. at 27. But, considering the litigation record in both the Glenmark and Mylan patent disputes, especially as detailed by Plaintiffs' patent merits expert, Hrubiec, reasonable jurors could conclude Merck's settlement with Glenmark avoided a risk of patent invalidity and generic competition sufficient to invoke the rule of reason analysis.

The Glenmark case settled in 2010, two days before trial, and Merck faced immediate risk that its patent would be invalidated. Its Settlement Agreement avoided that risk and deferred competition from the Zetia first filer for years. To bring an antitrust claim on these facts, it is not necessary that the settlement close the door on all potential risk. Although the Mylan case also presented competitive risk to Merck when the parties settled in May 2010, the pending Mylan litigation did not prevent Merck from seeking to avoid the risk posed by the Glenmark

case. Actavis expressed "concern that a patentee [might use] its monopoly power to avoid the risk of patent invalidation or a finding of noninfringement." Actavis, 570 U.S. at 156.

Merck argues that Plaintiffs have conceded the absence of any objective evidence that Defendants would have evaluated the Mylan and Glenmark cases differently, and thus Merck must have "understood itself to face the exact same risk in both cases." Merck Reply (ECF No. 1213, at 22) (emphasis in original). This assertion ignores substantial evidence that the Mylan case proceeded to trial under a very different record. While future developments may not have been predictable at the time of settlement, the Mylan litigation was less than six months old. Merck also took extensive actions after the Glenmark settlement that, Plaintiffs contend, would have significantly improved its chances at trial against Mylan.

As set forth in the Hrubiec rebuttal report, they first obtained reissue of the RE'721 patent omitting compounds 4E and F. They designated a new expert on inventorship (Glenmark's strongest invalidity argument) and benefited from the Federal Circuit's tightening of the inequitable conduct standard in Therasense, 649 F.3d 1276. A reasonable juror could rely on this evidence and conclude that Merck would have evaluated the cases differently in May 2010. Indeed, the most fundamental evidence that it did

evaluate them differently is that Merck settled with Glenmark, but tried the case against Mylan.

The second argument -- that the Glenmark settlement did not allow Merck to "actually avoid[] any risk of competition" because it still had to contest Mylan's invalidity challenge -- can be disposed of for the same reason. Merck Mem. (ECF No. 1085, at 26). Merck argues that the Actavis inference depends on there being an unresolved question about the patent's validity. Id. (quoting Actavis, 570 U.S. at 147). Because Merck won against Mylan, Merck argues that it cannot have been acting to "shield a weak patent from any meaningful challenge" by settling with Glenmark. Id. at 27. But Merck did not know that it would win against Mylan when it settled with Glenmark. And thus, reasonable jurors could conclude that — when it agreed in 2010 to refrain from competing against Glenmark with an AG, it was using its monopoly power to obtain a more favorable (later) date for generic competition from Glenmark. At the same time, the settlement allowed Merck to re-set its trial strategy, obtain patent reissue, and strengthen its position to defeat the Mylan challenge. And under Plaintiffs' theory of an alternative settlement, Glenmark's entry date was fixed in the Settlement Agreement and no longer depended on Mylan or any subsequent filer successfully challenging the ezetimibe patents. Indeed, Glenmark launched its admittedly infringing generic under the terms of the Settlement Agreement

while the ezetimibe patent was still valid and in force. Had they negotiated a different date without the no-AG promises, that date would have likewise been fixed in the Settlement Agreement and would have permitted the same thing.

B. Plaintiffs Have Shown a Dispute of Material Fact on Antitrust Causation and Injury, or Evidence that the no-AG Agreement Caused Delay in Glenmark Reaching the Market with Generic Ezetimibe.

It is a basic principle of private actions under the antitrust laws that proving Defendants' engagement in anticompetitive behavior is not sufficient for Plaintiffs to recover.[26] Plaintiffs must also prove that the Settlement Agreement caused Glenmark to delay its generic entry date, and that Plaintiffs were harmed by that delay. The harm that results from this type of antitrust violation is higher pharmaceutical prices. In re Androgel Antitrust Litig. (No. II), No. 1:09-CV-955-TWT, 2018 WL 2984873, at *12 (N.D. Ga. June 14, 2018). Frequently "the questions of antitrust injury and causation are closely linked and most effectively analyzed together." In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 762 (E.D. Pa. 2015), aff'd, 868 F.3d 132 (3d Cir. 2017).

[26] Actavis itself was not a private action but an FTC enforcement action, where causation is not required. Actavis, 570 U.S. at 136; see also Thompson Everett, Inc. v. National Cable Adv. L.P., 57 F.3d 1317, 1325 (4th Cir. 1995).

Separately from their arguments on the sufficiency of the evidence of any anticompetitive agreement, Defendants argue that Plaintiffs fail to offer proof that the agreement actually delayed generic competition. They first contend that Plaintiffs have abandoned any argument that Glenmark would have continued to litigate its invalidity challenges and won or launched at risk, both points Plaintiffs concede. Plaintiffs remaining causation theory relies on economic modeling to predict the terms of an alternate settlement untainted by the anticompetitive conduct. Defendants argue the expert testimony underlying these alternative settlement models is unreliable and insufficient to create a dispute of material fact or causation. Glenmark Mem. (ECF No. 1037, at 36-45); Merck Mem. (ECF No. 1085, at 42-55). Defendants also contend that regulatory and manufacturing obstacles would have prevented generic entry by the dates Plaintiffs' experts predict. Glenmark Mem. (ECF No. 1037, at 45-50). Finally, they claim vindication of the patent in the Mylan litigation conclusively rebuts Plaintiffs' claims that the settlement caused any delay. Merck Mem. (ECF No. 1085, at 56). On each of these contested points Plaintiffs have identified competent, admissible evidence sufficient to create a triable issue on causation under the alternative settlement theory.

1. Plaintiffs' abandoned causation theories under Actavis.

Defendants argue that they are entitled to summary judgment on Plaintiffs' claims based on other theories under Actavis. Glenmark Mem. (ECF No. 1050, at 24-27); Merck Mem. (ECF No. 1085, at 39-40). In their complaint, Plaintiffs alleged that, without the no-AG provision, Merck and Glenmark would have continued to litigate with Glenmark eventually winning, or launching its product at risk before the litigation was finally concluded. See, e.g., DPPs' Am. Compl. ¶ 183 (ECF No. 128, at 58-59) (complaining that no-AG agreement was given "as a quid pro quo for Glenmark's agreement to drop its patent challenge"). Defendants argue that Plaintiffs have no evidence Glenmark would have refused to settle and continued to trial, or that Glenmark would have launched generic ezetimibe at risk.[27] Glenmark Mem. (ECF No. 1050, at 24-27); Merck Mem. (ECF No. 1085, at 39-40). Defendants ask for summary judgment on these theories.

Plaintiffs do appear to have abandoned these theories. They do not devote space in their opposition to defending them. Hrubiec offered no opinion on either theory. Hrubiec Dep. 32:10-33:2, 37:18-38:1 (ECF No. 1151-10, at 33-34, 38-39). McGuire and Leffler

[27] A generic manufacturer launches "at risk" when the 30-month stay imposed by Hatch-Waxman expires – permitting FDA approval under the ANDA, but the patent issues remain unresolved. Entry of the allegedly infringing generic then risks the ordinary consequences of marketing an infringing product. In re Modafinil Antitrust Litig., 837 F.3d, at 244.

do not offer models based on these versions of the but-for world. See McGuire Dep. 207:16-208:24 (ECF No. 1087-1, at 35-36); Leffler Dep. 137:18-21 (ECF No. 1082-20, at 23). Thus, as part of its eventual ruling on the motion for summary judgment the court should clarify that Plaintiffs are precluded at trial from presenting these theories to the jury. A point conceded by counsel at oral argument. Hearing Tr., at 81-82. (ECF No. 1693).

2. Plaintiffs' alternative settlement causation theory.

Plaintiffs' remaining causation theory is that without the no-AG provision, Glenmark and Merck would still have settled, but with an earlier generic entry date. See Pls.' Opp'n (ECF No. 1156, at 69). This theory does not reflect the facts of Actavis, and as Glenmark points out, the Fourth Circuit has not explicitly recognized it. Glenmark Mem. (ECF No. 1050, at 27-28).

However, other circuits have analyzed pay-for-delay cases with alternative settlement causation theories. See In re Androgel Antitrust Litig. (No. II), No. 1:09-CV-955-TWT, 2018 WL 2984873, at *16 (N.D. Ga. June 14, 2018) (collecting cases that "endorsed this approach") (citing Wellbutrin, 133 F. Supp. 3d at 757; Lidoderm, 296 F. Supp. 3d at 1162; In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 563144, at *21-23 (D. Mass. Jan. 25, 2018)). The Northern District of California analogized using alternative settlement models in pay-for-delay cases to other patent cases that use hypothetical

negotiations to establish reasonable royalty rates, which is "a legal construct that attempts to ascertain the [terms] upon which the parties would have agreed had they successfully negotiated an agreement" at the relevant point in time. Lidoderm, 296 F. Supp. 3d at 1162 (quoting Fujifilm Corp. v. Motorola Mobility LLC, No. 12-CV-03587-WHO, 2015 WL 1737951, at *2 (N.D. Cal. Apr. 8, 2015)) (cleaned up); see also, Androgel, 2018 WL 2984873, at *17; Solodyn, 2018 WL 563144, at *21.

Plaintiffs rely on alternative settlement bargaining models from experts McGuire and Leffler. McGuire predicts that an economically rational settlement without a reverse payment would have allowed generic entry "between January 2015 and May 2015," McGuire Reb. Rpt. T2 (ECF No. 1130-9, at 26), while Leffler identifies April 1, 2015, Leffler Rpt. ¶ 85 (ECF No. 1130-4, at 54-55). Both experts rely on evidence from Plaintiffs' patent merits expert, Robert Hrubiec, regarding the strength of the Defendants' litigation position in 2010, and the expected length of time until these proceedings were concluded. Hrubiec Rpt. ¶ 52 (ECF No. 1083-18, at 29-31). Hrubiec's testimony, though contested, is reliable, admissible evidence properly offered to rebut Defendants' claims for summary judgment.

Defendants argue that the models "are incapable of creating a genuine issue of material fact sufficient to survive summary judgment." Glenmark Mem. (ECF No. 1050, at 42). They do not

contest the legal basis for an alternative settlement model as evidence, but criticize the inputs for the McGuire and Lefler Models, particularly Hrubiec's testimony. These arguments essentially rehash the concerns they raised in their Daubert motions opposing those experts. See id. at 36-45; Merck Mem. (ECF No. 1085, at 42-55). My opinions on the reliability of McGuire's, Leffler's, and Hrubiec's opinions are laid out in detail elsewhere, and I will not revisit those conclusions here. (ECF Nos. 1648, 1649) (denying motions to exclude). As Defendants concede, economic modeling of the type McGuire and Leffler employ is frequently and reliably employed in antitrust cases which present the problem of analyzing a hypothetical but-for world unaffected by the anticompetitive conduct. Lidoderm, 296 F. Supp. 3d, at 1162. Other courts have regularly relied on similar evidence from these experts and others to deny summary judgment on the alternative settlement theory. Androgel, 2018 WL 2984873, at *17 (relying on expert opinions from Leffler and Prof. Elhauge that it would be "economically rational" for generic to settle without a reverse payment and an earlier entry date); Lidoderm, 296 F. Supp. 3d at 1163 (finding testimony from economic experts Leffler and Elhauge "fully consistent with the principles applied in but-for damage calculations"). Solodyn, 2018 WL 563144, at *23 (concluding "expert opinions of McGuire and Leffler [present] sufficient factual support to withstand summary judgment").

Having found these experts' testimony sufficiently reliable under Daubert and Rule 702, it is adequate to support Plaintiffs' arguments against summary judgment.

3. There is a dispute of material fact regarding whether Glenmark or other generic manufacturers could have entered the market early if the patent were invalidated.

In order to prove causation and injury, Plaintiffs must show that generic competition would have commenced earlier in the but-for world. See In re Wellbutrin XL Antitrust Litig., 868 F.3d 132, 166 (3d Cir. 2017) (requiring "evidence affirmatively showing that [the first ANDA filer] could have launched"). Glenmark argues that Plaintiffs cannot show that it (or other generic manufacturers) would have competed with branded Zetia any earlier. Glenmark Mem. (ECF No. 1050, at 46). However, Plaintiffs have provided sufficient evidence to permit a reasonable jury to conclude that Glenmark and other manufacturers could have launched, and that they would have done so.

a. There is a dispute of material fact about whether Glenmark had the manufacturing capacity to launch.

Glenmark claims that it could not "manufacture sufficient quantities of ezetimibe for commercial launch earlier than it actually did." Glenmark Mem. (ECF No. 1050, at 47). But, the facts Glenmark points to in support of this assertion all relate to the timeline and difficulties the company encountered in the Actual World. They are therefore affected by the Settlement Agreement's

allegedly anticompetitive entry date in December 2016. To show that Glenmark could have met the requisite demand, Plaintiffs proffer expert Susan Marchetti, who testifies that — in the But For World — Glenmark could have launched on November 15, 2014, or anytime later, by using MSN Labs' API. See Pls.' Opp'n (ECF No. 1156, at 85-87); Marchetti Rpt. ¶ 97 (ECF No. 1148-13, at 40). Glenmark argues that the court should ignore Marchetti's testimony because it "is not grounded in any record evidence" about MSN Labs. Glenmark Mem. (ECF No. 1050, at 49). However, Marchetti's testimony is sufficiently reliable to create a dispute of material fact on this issue.

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. United States v. Wilson, 484 F.3d 267, 274-75 (4th Cir. 2007). As the Fourth Circuit noted in Wilson, "experiential expert testimony . . . does not rely on anything like a scientific method." Id. at 274 (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments) (cleaned up). Nevertheless, the court's gatekeeping role "is to make certain that an expert employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 200 (4th Cir. 2001) (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999)) (cleaned up). Courts must still require an experiential expert to "explain how his experience leads to the

conclusion reached, why his experience is a sufficient basis for the opinion, and how his experience is reliably applied to the facts." Wilson, 484 F.3d at 274 (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments) (cleaned up).

Marchetti is sufficiently qualified to offer this opinion. Marchetti has over 35 years of experience at brand and generic pharmaceutical companies. Marchetti Rpt. ¶ 5 (ECF No. 1148-13, at 5). She has worked in supply chain operations at companies "whose sole mission was to be first to market with generic drugs" no longer patented, and she understands the production steps for launching a generic product. Id. ¶ 5-7 (ECF No. 1148-13, at 5-6). In fact, she has worked on the launch of more than 60 generic products. Id. ¶ 7. Glenmark does not challenge Marchetti's experience in the relevant field.

Glenmark's main concern with Marchetti is that she did not know enough about MSN Labs in particular. Glenmark Mem. (ECF No. 1050, at 48). Plaintiffs did not take formal discovery from MSN Labs, and Marchetti bases her testimony about MSN Labs' capacity on evidence contained in other discovery, including COAs for ezetimibe MSN manufactured in 2013. Marchetti Rpt. ¶ 90 (ECF No. 1148-13, at 37). During her deposition, Marchetti testified that she did not know how MSN Labs structured its COA; have any information about MSN Labs' facilities, equipment, and workforce; or know the steps of MSN Labs' production process. Marchetti Dep.

124:20-125:9, 127:21-128:5, 261:7-14 (ECF No. 1039-27, at 5, 6, 10). Glenmark contends that, without more knowledge about MSN Labs, Marchetti cannot reliably interpret MSN Labs' COAs to reach her conclusions regarding the company's capacity. Glenmark Mem. (ECF No. 1050, at 48).

But Marchetti also testified that she did not need this information to understand the data reflected on the MSN Labs' COAs. From her experience, she considered that a suppliers' offer was evidence of capacity. Marchetti Dep. 124:20-126:1 (ECF No. 1039-27, at 5-6). Further, she interpreted the ezetimibe COAs using her experience. See Marchetti Dep. 284:15-21 (ECF No. 1039-27, at 14). Thus, Marchetti explained how her experience led to her conclusion. Defendants are free to cross-examine Marchetti about these concerns, but her testimony is not unreliable and it is probative of MSN's ability to supply Glenmark with sufficient quantities of the ezetimibe API.

Plaintiffs also supplied additional evidence in their briefing to support Marchetti's conclusions, including that in 2015, MSN Labs offered at least 250 kgs of API on an approximately monthly schedule using the same process as the 2013 batches reflected in the COAs. Pls.' Opp'n (ECF No. 1156, at 87). Defendants contend that 2015 data is not reflective of what MSN Labs could have provided in 2013. Glenmark Reply (ECF No. 1195, at 36). But Plaintiffs are operating in the But-For World. In

the Actual World, MSN Labs did not have any incentive to produce API for Glenmark in 2013, long before Glenmark would be able to market generic ezetimibe. The fact that it could produce the API in 2015 at a rate equivalent to the 2013 COAs could allow a reasonable juror to find that MSN Labs was capable of such production by November 2013, which is long before the date either expert identifies for early entry in their alternative settlement models of the But-For World.

b. There is a dispute of material fact about whether Glenmark and other generic manufacturers would have received regulatory approval to launch.

Glenmark argues that Plaintiffs cannot establish antitrust harm because they have no competent evidence that it, or its generic competitors could have obtained regulatory approval to enter the market earlier. Glenmark Mem. (ECF No. 1050, at 49-51). Plaintiffs counter that expert testimony from generic launch experts Jon Clark and Todd Clark is sufficient to create a dispute of material fact. I previously concluded that both the Clarks' opinion testimony was sufficiently reliable under Daubert and Rule 702. Mem. Op. and Order (ECF No. 1679). It is not necessary to repeat the entire rationale of that opinion here. It is sufficient to note that both experts — whose credentials were not in dispute — rely on an extensive factual record of the timing of FDA approval in the Actual World, to opine on reasonable dates for expected regulatory approval in a But-For World that was untainted by the

delayed entry date fixed in the allegedly anticompetitive Settlement Agreement. As with their challenge to other experts, Defendants complain that the experts' testimony does not align with Glenmark's Actual World decision-making. But as explained in the Memorandum Opinion, both Clarks are permitted to offer opinions based on the facts Plaintiffs expect to prove at trial. Mem. Op. (ECF No. 1679, at 21-22). Considering the evidence set forth in both Clark reports, and summarized in Plaintiffs' Summary Judgment briefing, they have established a dispute of material fact regarding generic manufacturers' ability to surmount any regulatory obstacles to earlier entry.

Relying on Jon Clark's testimony and the record facts, Plaintiffs allege that Glenmark would have obtained regulatory approval using its own DMF as early as January 2011. Pls. SOF ¶ 61, fn. 166 (ECF No. 1156, at 30). Had they instead relied on the API produced by MSN labs under a different process, they could have obtained approval by September 2013, and made sufficient inventory for launch by November 2014. Id. ¶¶ 64-67 (ECF No. 1156, at 31-32). Similarly, Todd Clark opined regarding regulatory approval for generic makers Teva and Sandoz no later than 180-days after Glenmark's entry. Id. ¶¶ 69-70 (citing T. Clark Reb. Rpt. ¶ 42) (ECF No. 1156, at 33). Reasonable jurors could rely on this evidence to conclude that regulatory obstacles would not have delayed entry of an ezetimibe generic in the But-For World.

4. There is a dispute of material fact about the relevance of the Mylan litigation.

Defendants also argue that Plaintiffs were not injured by the alleged anticompetitive conduct because the patent was found valid and enforceable in the Mylan litigation. Merck Mem. (ECF No. 1085, at 54-56); Merck Reply (ECF No. 1213, at 44-46). Cognizable antitrust injury requires that Defendants excluded lawful competition. See Wellbutrin, 868 F.3d at 165 ("It is not enough . . . to show that [the generic manufacturer] wanted to launch its drug; they must also show that the launch would have been legal."); see also Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 344-45 (1990). Defendants contend that, because the Mylan litigation established the patent's validity, the earlier launch dates predicted in the McGuire/Lefler models are irrelevant. The patent was valid at that time and Plaintiffs cannot be injured "from the failure to be able to buy Glenmark's infringing product sooner." Merck Mem. (ECF No. 1085, at 56).

This argument misapplies the theory of antitrust injury underlying Actavis and Plaintiffs' claims. The 2010 Merck/Glenmark Settlement Agreement is the source of anti-competitive harm. As explained elsewhere in this recommendation and other opinions, the court must approach that settlement from the viewpoint of the parties in May 2010, when they settled. See Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1306 (11th

Cir. 2003) ("[R]easonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into."); Polk Bros., Inc. v. Forest City Enters., Inc., 776 F.2d 185, 189 (7th Cir. 1985) (holding that "[a] court must ask whether an agreement promoted enterprise and productivity at the time it was adopted" and "the aftermath is the wrong focus").

The Settlement Agreement delayed generic competition from Glenmark and the period of that delay became certain once the Agreement was concluded. If Plaintiffs establish a no-AG provision in the Agreement, a large and unjustified payment for that delay will establish antitrust harm no matter the result of the Mylan case. Androgel, 2018 WL 2984873, at *11. "Paying [generics] to stay out of the market for the purpose of avoiding the risk of competition is an antitrust harm, regardless of whether not the patent is valid and infringed." Id. (emphasis in original). Actavis itself, and many decisions applying it, make clear that anticompetitive affects result from the patentholders' exercise of monopoly power, through payment or restrictive licensing, to avoid a risk of competition. Actavis, 570 U.S. at 157; King Drug, 791 F.3d at 406-07. The question is not one of patent law, but of antitrust law which prohibits the improper use of a patent monopoly. King Drug, 791 F.3d at 407 (citing Actavis, 570 U.S. at 148). The fact that Merck later defended a reissued version of the same patent may bear on the strength of the expert opinions

underlying causation and damages, but it is not a bar to liability as Defendants allege. Thus, the court should not grant summary judgment simply because Merck won that later litigation.

IV. RECOMMENDATION

For the foregoing reasons, this Report RECOMMENDS that the district court DENY Defendants' Motions for Summary Judgment on All Claims (ECF Nos. 1037, 1067).

V. REVIEW PROCEDURE

By copy of this Report and Recommendation, the parties are notified that pursuant to 28 U.S.C. § 636(b)(1)(C):

1. Any party may serve upon the other party and file with the Clerk written objections to the foregoing findings and recommendations within fourteen (14) days from the date of mailing of this Report to the objecting party, 28 U.S.C. § 636(b)(1)(C), computed pursuant to Rule 6(a) of the Federal Rules of Civil Procedure. A party may respond to another party's objections within fourteen (14) days after being served with a copy thereof.

2. A district judge shall make a de novo determination of those portions of this report or specified findings or recommendations to which objection is made.

The parties are further notified that failure to file timely objections to the findings and recommendations set forth above will result in waiver of right to appeal from a judgment of this court based on such findings and recommendations. Thomas v. Arn,

474 U.S. 140 (1985); Carr v. Hutto, 737 F.2d 433 (4th Cir. 1984); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984).

/s/
Douglas E. Miller
United States Magistrate Judge

DOUGLAS E. MILLER,
UNITED STATES MAGISTRATE JUDGE

September 2, 2022